

IN THE UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF TENNESSEE

JOAN M. PEAY,

Plaintiff,

v.

AMERIDOSE, LLC, MEDICAL SALES
MANAGEMENT, INC., MEDICAL SALES
MANAGEMENT SW, INC., GDC
PROPERTIES MANAGEMENT, LLC, ARL
BIO PHARMA, INC. D/B/A ANALYTICAL
RESEARCH LABORATORIES, BARRY J.
CADDEN, GREGORY CONIGLIARO, LISA
CONIGLIARO CADDEN, DOUGLAS
CONIGLIARO, CARLA CONIGLIARO,
GLENN A. CHIN, SAINT THOMAS
OUTPATIENT NEUROSURGICAL CENTER,
LLC, HOWELL ALLEN CLINIC A
PROFESSIONAL CORPORATION, SAINT
THOMAS WEST HOSPITAL (formerly known
as SAINT THOMAS HOSPITAL), SAINT
THOMAS NETWORK and, SAINT THOMAS
HEALTH

Defendants.

Civil Action No. _____
JURY DEMAND

COMPLAINT

The Plaintiff, Joan Peay, for her cause of action against the Defendants respectfully states unto the Court as follows:

INTRODUCTION

1. This lawsuit arises as a result of a widespread outbreak of fungal meningitis over the past year that has affected people in at least 20 states and caused over 60 deaths. Over 700 people have been diagnosed with meningitis.

2. The United States Food and Drug Administration (“FDA”) and the Centers for Disease Control (“CDC”) have identified fungus present in several separate lots of preservative-free injectable steroids, specifically, methylprednisolone acetate (referred to herein as “MPA”), that was compounded and distributed by New England Compounding Pharmacy, Inc. d/b/a New England Compounding Center (“NECC”) as the cause of the fungal meningitis outbreak and the resulting injuries and deaths.

3. Many thousands of vials of steroids compounded at NECC have been recalled but this recall was too late for Plaintiff Joan Peay, and for many others, who have suffered serious and at times catastrophic injuries.

4. Upon information and belief, between May 2012 and September 2012, Saint Thomas Outpatient Neurosurgical Center, LLC (hereinafter referred to as “Saint Thomas Neurosurgical”) purchased thousands of vials of MPA from NECC and then sold and administered the MPA to patients including Ms. Peay.

5. On September 7, 2012, Ms. Peay received an epidural steroid injection (“ESI”) at Saint Thomas Neurosurgical. During this procedure, Ms. Peay was injected with MPA.

6. Ms. Peay’s September 7, 2012 injection came from one or more contaminated lots of MPA that were purchased from NECC, which were subsequently recalled by NECC.

7. Ms. Peay’s September 7, 2012 injection of MPA caused her personal injury.

PARTIES

8. Joan Peay is a citizen and resident of the State of Tennessee, residing at 2746 Riverbend Drive, Nashville, Davidson County, Tennessee 37214.

9. Defendant Ameridose, LLC (“Ameridose”) is a Massachusetts limited liability company organized and domesticated under the laws of the Commonwealth of Massachusetts with a principal place of business at 205 Flanders Road, Westborough, Massachusetts 01581.

The managers of Ameridose are Gregory Conigliaro and Barry Cadden. Ameridose's registered agent is Gregory Conigliaro.

10. Defendant Medical Sales Management, Inc. ("MSM") is a Massachusetts corporation organized and domesticated under the laws of the Commonwealth of Massachusetts with its principal place of business at 697 Waverly Street, Framingham, Massachusetts 01702. Douglas Conigliaro is the President and a Director of MSM. Barry Cadden is the Treasurer and a Director of MSM. Gregory Conigliaro is the Secretary and a Director of MSM. MSM's registered agent is Gregory Conigliaro.

11. Defendant Medical Sales Management SW, Inc. ("MSMSW") is a Massachusetts corporation organized and domesticated under the laws of the Commonwealth of Massachusetts with its principal place of business at 697 Waverly Street, Framingham, Massachusetts 01702. Douglas Conigliaro is the President and a Director, Barry Cadden is the Treasurer and a Director, Gregory Conigliaro is the Secretary and a Director and Lisa Conigliaro. MSMSW's registered agent is Gregory Conigliaro.

12. Defendant GDC Properties Management, LLC ("GDC"), is a Massachusetts limited liability company organized and domesticated under the laws of the Commonwealth of Massachusetts with its principal place of business at 701 Waverly Street, Framingham, Massachusetts 01702. GDC's manager and registered agent is Gregory Conigliaro.

13. Defendant ARL Bio Pharma, Inc. d/b/a Analytical Research Laboratories ("ARL") is an Oklahoma corporation organized and domesticated under the laws of the State of Oklahoma with a principal place of business at 840 Research Parkway, Suite 546, Oklahoma City, Oklahoma 73104. Thomas C. Kupiec is the Chief Executive Officer and registered agent of ARL.

14. Defendant Barry J. Cadden (“Barry Cadden”) is an individual residing at 13 Manchester Drive, Wrentham, Massachusetts 02093 and a citizen and resident of the Commonwealth of Massachusetts. Barry Cadden is the President of NECC, which is a Massachusetts corporation. At least until October 2012, Barry Cadden was NECC’s licensed Pharmacist Manager of Record. Barry Cadden is a founder and Manager of Ameridose and was involved in Ameridose’s day to day operations. Barry Cadden is the Treasurer and a Director of MSM and MSMSW.

15. Defendant Gregory Conigliaro (“Gregory Conigliaro”) is an individual residing at 1 Mountain View Drive, Framingham, Massachusetts 01701 and a citizen and resident of the Commonwealth of Massachusetts. Gregory Conigliaro is a principal owner and the general manager of NECC, as well as NECC’s Treasurer, Secretary, Vice President, registered agent, and one of its Directors. Gregory Conigliaro provided financial advice, oversaw day to day operations, and regularly appeared in the NECC facility. Gregory Conigliaro is the founder and a Manager of Ameridose and involved in Ameridose’s day to day operations. Gregory Conigliaro is Secretary and a Director of MSM and MSMSW.

16. Defendant Lisa Conigliaro Cadden (“Lisa Cadden”) is an individual residing at 13 Manchester Drive, Wrentham, Massachusetts 02093 and a citizen and resident of the Commonwealth of Massachusetts. Lisa Cadden is a board member, Director and, at least until October 2012, a pharmacist at NECC. Lisa Cadden, upon information and belief, compounded drugs and was involved in the day to day operations of NECC.

17. Defendant Douglas Conigliaro (“Douglas Conigliaro”) is an individual residing at 15 Hale Drive, Dedham, Massachusetts 02026 and a citizen and resident of the Commonwealth of Massachusetts. Douglas Conigliaro is the President and a Director of MSM and MSMSW.

Douglas Conigliaro, upon information and belief, is involved in the day to day operations of NECC, Ameridose, MSM, and MSMSW.

18. Defendant Carla Conigliaro ("Carla Conigliaro") is an individual residing at 15 Hale Drive, Dedham, Massachusetts 02026, and a citizen and resident of the Commonwealth of Massachusetts and is a Director of NECC.

19. Defendant Glenn A. Chin ("Glenn Chin") is an individual residing at 173 Mechanic Street, Canton, Massachusetts 02021 and a citizen and resident of the Commonwealth of Massachusetts. At least until October 2012, Glenn Chin was a pharmacist at NECC. Glenn Chin, upon information and belief, compounded drugs at NECC.

20. Defendant Saint Thomas Outpatient Neurosurgical Center, LLC, ("Saint Thomas Neurosurgical") is a Tennessee for-profit limited liability company. Saint Thomas Neurosurgical's principal place of business is located on the 9th floor of the Medical Plaza East office building on the Saint Thomas Hospital campus at 4230 Harding Pike in Nashville, Davidson County, Tennessee, 37205. Saint Thomas Neurosurgical's registered agent for service of process is Gregory B. Lanford, M.D., 2011 Murphy Avenue, Suite 301, Nashville, Tennessee, 37203. At all times while providing and selling drug products to Ms. Peay at Saint Thomas Neurosurgical, the physicians, nurses, staff, and other personnel were agents, apparent agents, employees or representatives of Saint Thomas Neurosurgical and were acting within the course and scope of their employment, agency, or apparent agency with Saint Thomas Neurosurgical. Accordingly, Saint Thomas Neurosurgical, under the doctrine of *respondeat superior*, is vicariously liable for any negligent acts and omissions of their employees, agents, or representatives committed in the course and scope of their employment or agency while providing and selling drug products to Ms. Peay.

21. Defendant Howell Allen Clinic A Professional Corporation, ("Howell Allen Clinic") is a Tennessee professional corporation with its principal place of business in Nashville, Davidson County, Tennessee. Howell Allen Clinic's registered agent for service of process is Gregory B. Lanford, M.D., 2011 Murphy Avenue, Suite 301, Nashville, Tennessee, 37203.

22. Defendant Saint Thomas West Hospital is a Tennessee non-profit corporation with its principal place of business located on the Saint Thomas West Hospital campus at 4220 Harding Pike in Nashville, Davidson County, Tennessee. Saint Thomas West Hospital was formerly known as St. Thomas Hospital. Saint Thomas West Hospital's registered agent for service of process is E. Berry Holt, III, Suite 800, 102 Woodmont Boulevard, Nashville, Tennessee, 37205. Hereinafter, Saint Thomas West Hospital shall be referred to as "St. Thomas Hospital."

23. Defendant Saint Thomas Network is a Tennessee non-profit corporation with its principal place of business located on the St. Thomas Hospital campus at 4220 Harding Pike in Nashville, Davidson County, Tennessee. Saint Thomas Network's registered agent for service of process is E. Berry Holt III, Suite 800, 102 Woodmont Boulevard, Nashville, Tennessee, 37205.

24. Defendant Saint Thomas Network was formerly known as Saint Thomas Health Services and is a successor of Saint Thomas Health Services.

25. Saint Thomas Network, as the successor of Saint Thomas Health Services, is a manager of Defendant Saint Thomas Neurosurgical.

26. Saint Thomas Network, as the successor of Saint Thomas Health Services, is an owner and/or member of the Defendant Saint Thomas Neurosurgical.

27. Defendant Saint Thomas Health is a Tennessee non-profit corporation with its principal place of business in Nashville, Davidson County, Tennessee. Saint Thomas Health's registered agent for service of process is E. Berry Holt III, Suite 800, 102 Woodmont Boulevard, Nashville, Tennessee, 37205.

28. Defendant Saint Thomas Health was formerly known as Saint Thomas Health Services and is a successor of Saint Thomas Health Services.

29. Saint Thomas Health, as the successor of Saint Thomas Health Services, is a manager of Defendant Saint Thomas Neurosurgical.

30. Saint Thomas Health, as the successor of Saint Thomas Health Services, is an owner and/or member of Defendant Saint Thomas Neurosurgical.

31. Defendants Saint Thomas Network and Saint Thomas Health are hereinafter referred to collectively as "Saint Thomas".

32. At the time of the events described herein, Defendants Saint Thomas and Howell Allen Clinic acted in concert to operate jointly the Defendant Saint Thomas Neurosurgical.

33. The individuals and entities described in paragraphs 9-19 are sometimes collectively referred to as the "NECC Related Defendants."

34. The individuals and entities described in paragraphs 16-32 are sometimes collectively referred to as the "Tennessee Defendants."

JURISDICTION AND VENUE

35. This Court has subject matter jurisdiction over the parties pursuant to 28 U.S.C. § 1331 because this action arises under the laws or treaties of the United States. Specifically this Court has jurisdiction pursuant to 28 U.S.C. § 1334(b) because as described herein this case is related to a case under title 11.

36. On December 21, 2012, NECC filed a petition for Bankruptcy protection under Chapter 11 of the Bankruptcy Code: New England Compounding Pharmacy, Inc., Debtor, United States Bankruptcy Court for the District of Massachusetts, Case no. 12:19882-HJB. A United States Trustee was subsequently appointed to administer the Bankruptcy Estate. The Bankruptcy Court has not yet established a deadline for the filing of claims against NECC's bankruptcy estate In re New England Compounding Pharmacy, Inc.

37. According to NECC's Bankruptcy Trustee, NECC has express contractual indemnification obligations including but not limited to Barry Cadden, Gregory Conigliaro, Lisa Cadden, Carla Conigliaro, Glenn Chin, GDC and MSM. Some if not all of the aforementioned individuals are insureds under NECC's insurance policies. Adversarial cases seeking recovery of damages for the benefit of the bankruptcy estate and its unsecured creditors have been filed in NECC's bankruptcy against each of the NECC Related Defendants.

38. This case is related to the NECC Bankruptcy because the outcome of the proceeding certainly could have some effect on the bankruptcy estate.

39. Lawsuits alleging death or injury based on contaminated MPA have been filed around the country. On February 12, 2013, the Judicial Panel on Multidistrict Litigation (MDL No. 2419) issued an order under 28 U.S.C. § 1407 transferring various federal-court proceedings to the United States District Court for the District of Massachusetts for coordinated or consolidated pretrial proceedings. The transferred actions are pending in the United States District Court for the District of Massachusetts in the Multidistrict Litigation action styled: IN RE: New England Compounding Pharmacy, Inc. Products Liability Litigation, United States District Court, District of Massachusetts, MDL No. 1:13-md-2419-FDS. The transferred cases

have been assigned to the Honorable F. Dennis Saylor, United States District Judge, for pre-trial proceedings and coordination.

40. Upon information and belief, all of the Tennessee Defendants presently intend to seek, and will seek, relief from the stay in order to pursue contribution or indemnity claims against NECC for all or some portion of the damages sought by this Complaint. In addition or in the alternative, all of the Tennessee Defendants presently intend to file, and will file, claims in NECC's bankruptcy proceeding seeking indemnification or contribution for all or some portion of the damages sought by this Complaint.

41. By Order dated May 31, 2013, Judge Saylor, ruled that the New England Compounding Pharmacy, Inc. Multi District Litigation Court has subject-matter jurisdiction over any cases pending in federal court or state court against entities or individuals "affiliated" with NECC whether or not NECC is named as a defendant. Those NECC affiliated entities and individuals referred to by Judge Saylor in his May 31, 2013 Order include the defendants described in paragraphs 9-19.

42. In addition, or in the alternative, this Court has subject-matter jurisdiction over all claims against the Tennessee Defendants pursuant to 28 U.S.C. § 1367 in that all claims are so related to claims in this action within the original jurisdiction of this Court that they form part of the same case or controversy under Article III of the United States Constitution.

43. Venue is proper and appropriate in the United States District Court for the Middle District of Tennessee pursuant to 28 U.S.C. § 1391(b)(2) in that all or a substantial part of the events and actions giving rise to the matters asserted in the Complaint occurred in Davidson County, Tennessee.

44. At all times relevant the Defendants were engaged in the business of developing, compounding, marketing, distributing, promoting, selecting, purchasing and/or selling or administering either directly, or indirectly steroids in the State of Tennessee from which they derived significant and regular income.

45. Defendants are subject to the jurisdiction of this Court in that they are generally present in Tennessee, have transacted business within the State of Tennessee, and acting individually and/or through their agents and employees have committed tortious actions and omissions in Davidson County, Tennessee that have proximately caused the injuries that are the subject of this lawsuit.

46. The NECC related Defendants are further subject to the jurisdiction of this Court as a result of contracting to supply goods and things in Tennessee, by conducting or soliciting business in Tennessee, by engaging in a persistent course of conduct in Tennessee, and by deriving substantial revenue from goods used or consumed or services rendered in Tennessee.

STATEMENT OF FACTS

47. NECC is an entity that has filed for bankruptcy and is protected by the automatic stay provisions of 11 U.S.C. § 362. Prior to NECC filing for bankruptcy, numerous plaintiffs including Joan Peay, the plaintiff herein, filed suit against NECC in Tennessee and other states, all of which were eventually removed and transferred to the United States District Court for the District of Massachusetts in the Multidistrict Litigation action styled: IN RE: New England Compounding Pharmacy, Inc. Products Liability Litigation, United States District Court, District of Massachusetts, MDL No. 1:13-md-2419-FDS.

48. NECC was a compounding pharmacy that compounded, distributed and/or sold drugs to purchasers throughout the United States, including Tennessee.

49. Upon information and belief, NECC was a privately-held company that was owned and controlled by Barry Cadden, Gregory Conigliaro, Douglas Conigliaro, Carla Conigliaro and Lisa Cadden.

50. Ameridose, GDC, MSM and MSMSW were affiliates of NECC at all relevant times.

51. At least until October 2012, Gregory Conigliaro was involved in co-managing day-to-day operations of NECC, MSM, MSMSW, Ameridose and GDC.

52. At least until October 2012, Lisa Cadden was a licensed pharmacist who, upon information and belief, compounded medications including MPA at NECC.

53. At least until October 2012, Glenn Chin was a licensed pharmacist who, upon information and belief, compounded medications including MPA at NECC.

54. At least until October 2012, Barry Cadden was a licensed pharmacist. In addition to being NECC's President, Barry Cadden was NECC's licensed Pharmacist Manager of Record. Upon information and belief, Barry Cadden compounded medications including MPA at NECC.

55. "Manager of Record or Pharmacist Manager of Record," as defined by 247 CMR 2.00, "means a pharmacist, currently registered by the [Massachusetts] Board [of Registration in Pharmacy] pursuant to 247 CMR 6.07, who is responsible for the operation of a pharmacy or pharmacy department in conformance with all laws and regulations pertinent to the practice of pharmacy and the distribution of drugs."

56. Ameridose, according to an application signed by Gregory Conigliaro and filed with the Massachusetts Board of Registration in Pharmacy on May 14, 2012, is a "distribution center to entities of common ownership – currently Ameridose and NECC, as well as other Properly Licensed Facilities in the future."

57. On information and belief, upon the direction of NECC's principals, on April 11, 2011, Ameridose employee Michelle Rivers requested certification for pharmacy technicians employed by NECC for use in an inspection of NECC's facilities by the Massachusetts Board of Registration in Pharmacy.

58. On or about August 24, 2012, Ameridose posted an employment opportunity for Registered Pharmacists to work for NECC in Framingham, Massachusetts. In the posting, potential applicants were told to contact mlord@medicalesalesmgmt.com. Upon information and belief, there were many other occasions where employees of Ameridose, MSM and/or MSMSW would perform services for NECC at the direction of NECC's principals.

59. Between 2006 and the present, Ameridose and NECC would often share a booth at conferences and conventions with a single banner listing both company names. During that same time, Ameridose and NECC would hold an annual Christmas party for employees of both companies.

60. MSM and/or MSMSW printed materials for and marketed both NECC's and Ameridose's products, including MPA. One former employee of MSM and/or MSMSW has stated: "I didn't think there was any difference [between Ameridose and NECC]."

61. Through September 2012, both NECC and Ameridose used MSM and/or MSMSW for sales and marketing functions. NECC's privacy policy on its website referred to the "Ameridose Privacy Policy." In 2012, NECC salespersons recommended NECC's "sister company," Ameridose, for drug compounds that NECC did not have available.

62. MSM and/or MSMSW shared office space owned by GDC Properties with NECC in Framingham, Massachusetts.

63. Since it was formed as a limited liability company in 2006, Ameridose has been controlled by NECC.

64. Both Ameridose and NECC were controlled by Conigliaro and Cadden family members.

Claims against the NECC Related Defendants

65. NECC has a well-known history of adverse events relating to its operation as a compounding pharmacy. According to the Majority Memorandum for the November 14, 2012 Oversight and Investigations Subcommittee Hearing, NECC has been the subject of multiple complaints to and investigations by the FDA and the Massachusetts Board of Registration in Pharmacy (“MBP”) over the past decade often focusing on unsterile conditions at NECC’s facilities. For example, the FDA issued a Warning Letter to NECC in 2006. The FDA letter details numerous problems at NECC including the sale of compounded drugs without patient-specific prescriptions, compounding copies of commercially available drugs, selling misbranded compounded drugs, and problems with storage and sterility. That warning letter has been available to the public on the FDA’s website for years.

66. Between January 2012 and August 2012, NECC’s environmental monitoring program for its compounding facility yielded numerous microbiological isolates (bacteria and mold) within the Clean Room used for the production of methylprednisolone acetate. NECC, Barry Cadden, Gregory Conigliaro, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro, Glenn Chin, Ameridose, MSM and/or MSMSW and GDC knew or should have known of these findings. NECC, Barry Cadden, Gregory Conigliaro, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro, Glenn Chin, Ameridose, MSM and/or MSMSW and GDC failed to investigate those isolates and made no effort to identify those isolates. NECC, Barry Cadden, Gregory Conigliaro, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro, Glenn Chin, Ameridose, MSM and/or

MSMSW and GDC failed to perform any product assessments for the products made in the Clean Room where the isolates were found. NECC, Barry Cadden, Gregory Conigliaro, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro, Glenn Chin, Ameridose, MSM and/or MSMSW and GDC failed to take any corrective actions with regards to the isolates that were found. Despite these findings, NECC continued to compound MPA, and Ameridose, MSM and/or MSMSW continued to distribute marketing materials to customers and potential customers touting the cleanliness of the NECC laboratories.

67. On September 26, 2012 in the wake of dozens of cases of fungal meningitis associated with NECC's injectable steroid MPA, state agents raided NECC's lab in a strip mall on Waverly Street in Framingham, Massachusetts.

68. NECC's few remaining employees were scrubbing the compounding areas with bleach. Despite this last-ditch effort, the "clean" rooms were filthy. A leaky boiler stood in a pool of stagnant, dirty water. The autoclaves used to sterilize the product were discolored, tarnished, and contained visible moisture. The air intake came from vents located about 100 feet from a mattress recycling facility that released copious amounts of dust and other contaminants into the air. The air vents in the "clean" rooms were covered with dirt and white fuzz. The metal shelf in the "clean" room used to prepare MPA was covered in a reddish-brown, cloudy substance.

69. Investigators determined that NECC's internal records showed dozens of instances of bacterial and fungal contamination within the NECC facility over at least the past nine months. NECC ignored these test results. NECC never even attempted to get rid of these microbial contaminants.

70. Eighty-three out of three-hundred twenty one observed vials from one of three recalled lots of MPA contained a greenish-black substance visible to the human eye. Seventeen other vials contained a white filamentous material. All fifty out of fifty vials tested confirmed the presence of live microbes (whether fungal or bacterial). The CDC and FDA later confirmed the presence of fungus in unopened vials of NECC's MPA. This is the same fungus that the CDC confirmed was present in at least forty fungal meningitis cases.

71. Inspections of NECC's sister company Ameridose revealed similarly deplorable conditions, including countless instances of visible contamination of the hoods and rooms used to prepare drug products, insect infestations, birds flying through areas where purportedly sterile products were packaged and stored, and tubs being used to collect rain water that poured through the chronically leaky roof above the "clean" rooms. Ameridose, like NECC, persistently ignored and failed to investigate at least fifty-three instances of known microbiological contamination. Ameridose also hid adverse events associated with its products, failing to report them to the FDA as required by law and instead classifying these events as "patient responses" or "non-complaints" and taking no action to address them.

72. The CDC determined that three lots of 80 mg/ml MPA produced by NECC between May 21 and September 26, 2012 were contaminated with potentially deadly pathogens.

73. In late September 2012, NECC recalled the following lots of MPA (PF) 80 mg/ml that it had compounded and sold: MPA (PF) 80 mg/ml Injection, Lot #05212012@68, BUD 11/17/2012; MPA (PF) 80 mg/ml Injection, Lot #06292012@26, BUD 12/26/2012; and MPA (PF) 80 mg/ml Injection, Lot #08102012@51, BUD 2/6/2013.

74. NECC identified Defendant Saint Thomas Neurosurgical as one of the healthcare providers that received vials of MPA that were part of the September 2012 recall.

75. On or about October 3, 2012, the Massachusetts Department of Public Health (“DPH”) secured the surrender of NECC’s license to operate as a compounding pharmacy.

76. On October 6, 2012, NECC announced that it was recalling “all products currently in circulation that were compounded at and distributed from its facility in Framingham, Massachusetts.”

77. On or about October 8, 2012, at the request of DPH, Barry Cadden and Glenn Chin “voluntarily” ceased their practice as pharmacists. Lisa Cadden also has “voluntarily” ceased her practice as a pharmacist. Upon information and belief, none of them have practiced as a pharmacist since “voluntarily” ceasing their practice.

78. On or about October 22, 2012, the Massachusetts Board of Registration in Pharmacy authorized DPH to request the “voluntary” permanent surrender of the licenses of Barry Cadden, Glenn Chin, Lisa Cadden and NECC. According to DPH, “[i]f the three pharmacists and NECC do not comply, the Board authorized staff to proceed with permanent revocation.”

79. One of the Massachusetts regulations promulgated by the Massachusetts Board of Registration in Pharmacy pertinent to NECC’s operation as a compounding pharmacy mandated that “[t]he premises of the pharmacy or pharmacy department shall at all times be kept in a clean and sanitary manner.” 247 CMR 6.02(1).

80. Over the last ten years, ARL has conducted sterility testing on samples of MPA compounded by NECC, including samples from Lot #05212012@68, BUD 11/17/2012; Lot #06292012@26, BUD 12/26/2012; and Lot #08102012@51, BUD 2/6/2013.

81. From May through August 2012, NECC sent several samples of its MPA to ARL for sterility testing. As one example, on or about May 21, 2012, NECC sent to ARL two 5ml

vials of MPA from a batch of 6,528 vials that came from Lot 05212012@68, which had been compounded by NECC on May 21, 2012.

82. On May 22, 2012, ARL received and tested the two 5ml vials of MPA that NECC sent to ARL on or about May 21, 2012. ARL sent to NECC a Microbiology Report dated May 25, 2012, which stated that the two vials had been tested on May 22, 2012 and that the “preliminary” results from the sterility test using test method USP 71 showed that the two 5ml vials of MPA that NECC sent to ARL on or about May 21, 2012, were “sterile.” ARL’s report to NECC further noted that the preliminary results were observed “after approximately 72 hours of incubation.”

83. Pursuant to the protocols of test method USP 71, sterility testing on a batch of more than 6,000 vials of MPA should have been conducted on at least 20 vials from the batch.

84. On or about August 10, 2012, NECC caused one 5ml vial of MPA to be sent to ARL for sterility testing from a batch of several thousand vials that are from Lot #08102012@51, BUD 2/6/2013.

85. The Microbiology Reports issued by ARL to NECC between May and September 2012 concerning the sterility testing of MPA indicated that the sterility tests performed by ARL were conducted in compliance with USP 71.

86. During the summer of 2012, MSM and/or MSMSW sales representatives, on behalf of NECC and Ameridose, distributed copies of the May 25, 2012, ARL Microbiology Report concerning the testing of the vials of MPA from Lot 05212012@68 to customers and/or potential customers in a packet of marketing materials intended to highlight the safety and sterility of the MPA compounded by NECC.

87. ARL was aware of the risks posed by compounding pharmacies, specifically including the risks posed by NECC's compounding practices.

88. In 2002, ARL found that four samples of a steroid compounded by NECC were contaminated with potentially deadly endotoxins.

89. ARL allowed compounding pharmacies such as NECC to submit an inadequate number of samples for sterility testing, which practice did not comply with USP 71 requirements.

90. GDC which is an acronym for "Gregory D. Conigliaro" owns the real property and is responsible for maintenance and structural improvements at 685-705 Waverly Street, Framingham, Massachusetts.

91. From 1998 until at least October 2012, GDC leased a portion of the premises at Waverly Street to NECC, MSM and MSMSW.

92. In an on-line posting for a property management position at GDC, which appeared on or before October 25, 2012, GDC stated that it "owns an 88,000 square foot facility on seven acres in downtown Framingham. GDC currently has eight major tenants." GDC described one of the duties and responsibilities of the GDC property manager as follows: "Insure all tenants operate their businesses in accordance with facility, local [and] state . . . rules and regulations."

93. GDC maintained a high degree of control over the premises leased by NECC.

94. Until October 2012, NECC, Ameridose, ARL, Barry Cadden, Lisa Cadden, and Glenn Chin compounded, tested, marketed and/or distributed MPA.

95. GDC and Gregory Conigliaro knew that NECC was compounding preservative-free MPA at 697 Waverly Street, and further knew that this medication was injected into humans and was required to be sterile.

NECC and Risks of Pharmacy Compounding

96. The serious risks of pharmacy compounding were also the subject of considerable public discussion in the pharmacy community and the medical community before the subject fungal meningitis outbreak. The risks associated with compounded drugs have been known for years.

97. In 2002, the CDC published a report regarding at least two cases of fungal meningitis arising from contaminated medication used in epidural injections. The report concluded that “purchasers of pharmaceuticals should determine if supplies are provided from a compounding pharmacy that...follows appropriate measures to ensure that injectable products are free of contamination.”

98. On March 24, 2005, *USA Today* published a front page article with the following headline: “**Safety concerns grow over pharmacy-mixed drugs**”. That article discussed growing concern over the fact that drugs produced in bulk by compounding pharmacies are not FDA approved and are not subject to the same oversight as drugs produced by pharmaceutical companies.

99. In 2006, the FDA conducted a survey of compounded drug products. They collected thirty-six samples from compounding pharmacies across the United States during unannounced visits. Twelve of the 36 samples (33%) failed analytical testing. The FDA survey concluded “poor quality compounded drugs are a serious public health concern, as improperly compounded products have been linked to grave adverse events, including deaths.”

100. In May 2007, the FDA published an article titled “The Special Risks of Pharmacy Compounding.” That article highlighted numerous adverse events involving compounded

products. It also warned of the emergence of large scale compounding operations that were clearly operating outside the bounds of traditional compounding practice.

101. In 2010, the FDA posted an educational video on YouTube regarding concerns over the quality of compounded drugs.

102. On November 5, 2010, the American Society of Anesthesiologists, the American Society of Health-System Pharmacists (“ASHP”) and other medical societies published a joint report regarding drug shortages. That report included an article written by the ASHP stating as follows:

Compounding pharmacies have also pursued the production of drugs that are in short supply. Caution is warranted because preparations from these pharmacies may not meet applicable state or federal standards (e.g., United States Pharmacopeia chapter 797 or FDA labeling requirements). The sources of raw materials used by compounding pharmacies have been questioned, and apparent lapses in quality control have resulted in serious patient injury, including death. Compounding pharmacies may also present patient risks; several deaths have been associated with improperly sterilized compounded products.

103. In May 2012, the CDC published a report regarding fungal infections arising from medications obtained from a compounding pharmacy. That report advised that “contamination of compounded sterile preparations has caused outbreaks. Since 1990, FDA has learned of approximately 200 adverse events associated with 71 compounded products.”

Fungal Meningitis Outbreak

104. In September 2012, health officials identified an outbreak of fungal meningitis which investigators traced back to the MPA compounded by NECC.

105. According to the CDC, fungal meningitis occurs when the protective membranes covering the brain and spinal cord are infected with a fungus. Fungal meningitis is rare and usually caused by the spread of a fungus through blood to the spinal cord. Fungal meningitis is not transmitted from person to person.

106. According to the CDC, symptoms of meningitis include the following: new or worsening headache; fever; sensitivity to light; stiff neck; new weakness or numbness in any part of the body; slurred speech; and increased pain, redness or swelling at the injection site. Death may result from meningitis.

107. According to the CDC, symptoms of fungal meningitis are similar to symptoms of other forms of meningitis; however, they often appear more gradually and can be very mild at first. In addition to typical meningitis symptoms, like headache, fever, nausea, and stiffness of the neck, people with fungal meningitis may also experience confusion, dizziness, and discomfort from bright lights. Patients might just have one or two of these symptoms.

Ms. Peay is injected with MPA from NECC and Suffers Personal Injury

108. On September 7, 2012, Ms. Peay was injected by Dr. Steven Dickerson at the Saint Thomas Neurosurgical with MPA.

109. Ms. Peay's September 7, 2012 injection came from one or more contaminated lots of MPA purchased from NECC. The contaminated lots were subsequently recalled by NECC.

110. Ms. Peay's September 7, 2012 injection of MPA caused her personal injury.

111. Ms. Peay had unusual soreness a few weeks after this injection and on, or about, September 27, 2012 she began to experience the onset of symptoms including severe headache, stiff neck, neck pain, fever, nausea and vomiting.

112. Ms. Peay became aware of the outbreak of fungal meningitis on, or about, October 1, 2012 based upon media reports in the Nashville, Tennessee metropolitan area which she viewed on the late evening news.

113. On the morning of October 2, 2012, Plaintiff contacted her physician's office, the Howell Allen Clinic, and spoke to a nurse practitioner who advised her, based upon her symptoms, to seek medical care immediately.

114. Plaintiff presented on October 2, 2012 at the emergency room of St. Thomas Hospital complaining of symptoms including severe headache, stiff neck, neck pain, fever, nausea and vomiting, all of which are symptoms indicative of fungal meningitis.

115. Plaintiff thereafter underwent diagnostic testing, including a lumbar puncture (spinal tap), and was diagnosed to be suffering from fungal meningitis. Plaintiff was then admitted to St. Thomas Hospital for treatment of fungal meningitis, where she remained for treatment for several months.

116. During her hospitalization, Ms. Peay treated with an IV solution of the anti-fungal medication Voriconazole, which caused her many severe side-effects, including vision disturbance, and the effects of which are unknown in the long-term.

117. After her discharge from Saint Thomas Hospital, Ms. Peay continued to be treated at home with IV Voriconazole and later with oral Voriconazole in pill form, all of which lasted many months.

118. Ms. Peay did not discover, and reasonably could not have discovered, until October 2, 2012 that she had received an injection of contaminated MPA.

119. Ms. Peay has suffered and continues to suffer harm, injury, and damages as a result of her exposure to one or more of the three recalled contaminated lots of MPA.

CAUSES OF ACTION

COUNT I - NEGLIGENCE (Against NECC Related Defendants)

120. As the designer, tester, compounder, seller, marketer and/or distributor of consumer products, the NECC related Defendants owed a duty to Ms. Peay to comply with existing standards of care, and to exercise due care, in providing a safe and quality product to Ms. Peay.

121. Specifically, but without limitation:

- a. Ameridose, MSM/MSMSW, GDC, Barry Cadden, Gregory Conigliaro, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro and Glenn Chin owed Ms. Peay a duty to provide MPA that was safe and free of contamination.
- b. ARL owed Ms. Peay a duty to properly conduct tests to insure that the MPA was safe and free of contamination.
- c. NECC Related Defendants sold MPA in bulk to Saint Thomas Neurosurgical, but they were not authorized to compound and sell MPA in bulk, instead they were only allowed to fill individual prescriptions for individual patients written by appropriately licensed health care providers.

122. Defendants breached those duties, and were otherwise negligent in their design, compounding, sale, testing, marketing and distribution of the recalled steroid medication, which was administered to Ms. Peay. The Defendants failed to exercise due care in accordance with the standard of care and skill required of, and ordinarily exercised by, a designer, compounder, tester, seller, marketer and distributor of steroid medications, as licensed to do so by the Commonwealth of Massachusetts. The Defendants, by and through their supervisors, staff and agents engaged in designing, compounding, storing, testing, selling, marketing and distributing MPA in a negligent manner.

123. Defendants further breached those duties by failing to properly design, compound, test and distribute MPA so that it would not be contaminated with fungus; by failing to properly maintain its facilities where it compounded its medications in a clean, sanitary manner; by failing to oversee the security and quality control of its compounding and distribution facilities; by allowing contaminated and unsafe compounded medications to reach the stream of commerce for use by Ms. Peay; and by failing to hold the components of the recalled MPA.

124. Ameridose, MSM/MSMSW, GDC, ARL, Barry Cadden, Gregory Conigliaro, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro and Glenn Chin breached the duties owed to

Ms. Peay by failing to use reasonable care in designing, compounding, testing, marketing, distributing and/or selling MPA.

125. The negligence of Ameridose, MSM/MSMSW, GDC, ARL, Barry Cadden, Gregory Conigliaro, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro and Glenn Chin was a proximate cause of Ms. Peay's injuries and damages.

COUNT II - NEGLIGENCE PER SE

(Against all NECC Related Defendants except ARL)

126. Ameridose, MSM/MSMSW, GDC, Barry Cadden, Gregory Conigliaro, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro and Glenn Chin owed Ms. Peay a duty to maintain the premises of the pharmacy "in a clean and sanitary manner[.]" 247 CMR 6.02(1), and free from contamination.

127. Ameridose, MSM/MSMSW, GDC, Barry Cadden, Gregory Conigliaro, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro and Glenn Chin breached the duties owed to Ms. Peay by failing to use reasonable care in maintaining the premises of the pharmacy "in a clean and sanitary manner[.]" 247 CMR 6.02(1), and free from contamination.

128. Defendants also violated Massachusetts' laws and its pharmacy licensing obligations.

129. The aforementioned actions by Ameridose, MSM/MSMSW, GDC, Barry Cadden, Gregory Conigliaro, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro and Glenn Chin were a proximate cause of Ms. Peay's injuries and damages.

COUNT III - NEGLIGENT SUPERVISION

(Against NECC Related Defendants)

130. Defendants Ameridose, MSM/MSMSW, GDC, ARL, Barry Cadden, Gregory Conigliaro, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro and Glenn Chin had an obligation and duty to exercise due care, and comply with the then existing standard of care, to

investigate and hire professional and competent employees to create, test, package, market and distribute the compounded medications and to maintain the facility and its premises, and to make sure the compounded drugs did not create any harm or risk to Ms. Peay and others who received the compounded medication.

131. In breach of those duties, Defendants failed to exercise due care and failed to supervise their employee(s) or agent(s), who were at all times working within the scope of their employment and authority. Specifically, and without limitation:

- a. The Defendants failed to monitor and test the steroid medication and were otherwise negligent in supervision of their employees.
- b. Defendants also failed to monitor and supervise the testing of the compounded medications.
- c. The Defendants were negligent in hiring, training, and supervising their employees.

132. The Defendants knew, or should have known, that their employee(s) or agent(s) did not follow proper procedures and knew or should have known of the risks created by failing to do so.

133. As a direct and proximate cause of the breach of those duties, the Defendants permitted the steroid to become contaminated and distributed to patients including Ms. Peay.

134. The aforementioned acts or omissions by Ameridose, MSM/MSMSW, GDC, ARL, Barry Cadden, Gregory Conigliaro, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro and Glenn Chin were a proximate cause of Ms. Peay's injuries and damages.

COUNT IV - PUBLIC NUISANCE
(Against Barry Cadden, Gregory Conigliaro and GDC)

135. At all relevant times, Barry Cadden, Gregory Conigliaro and/or GDC were in control of the property and improvements at 697 Waverly Street, Framingham, Massachusetts.

136. Barry Cadden, Gregory Conigliaro and GDC owed a duty to maintain the property and improvements at 697 Waverly Street, Framingham, Massachusetts in a condition that was free from contamination.

137. Barry Cadden, Gregory Conigliaro and GDC failed to exercise reasonable care in maintaining the property and improvements at 697 Waverly Street, Framingham, Massachusetts.

138. The failure by Barry Cadden, Gregory Conigliaro and GDC to maintain the property and improvements at 697 Waverly Street, Framingham, Massachusetts was a proximate cause of the multistate epidemic of fungal meningitis and infections caused by the contaminated MPA.

139. Barry Cadden, Gregory Conigliaro and GDC unreasonably and significantly interfered with the public health and the public safety.

140. Barry Cadden, Gregory Conigliaro and GDC unreasonably and significantly interfered with the public right expressed in 247 CMR 6.02(1).

141. The public nuisance created by Barry Cadden, Gregory Conigliaro and GDC was a proximate cause of Ms. Peay's injuries and damages.

142. The public nuisance created by Barry Cadden, Gregory Conigliaro and GDC has caused Ms. Peay special injury in that she has sustained injuries to her personal health.

COUNT V - PRODUCT LIABILITY CLAIMS
(Against the Tennessee Defendants)

143. The MPA injected into Ms. Peay on September 7, 2012 was compounded by NECC.

144. On December 21, 2012, NECC filed a voluntary petition pursuant to Chapter 11 of Title 11 of the United States Bankruptcy Code in the United States Bankruptcy Court for the

District of Massachusetts, In re: New England Compounding Pharmacy, Inc., No. 12-19882-HJB.

145. Pursuant to 11 U.S.C. § 362(a) (1) certain actions against NECC are stayed following its bankruptcy petition.

146. Ms. Peay's claims that arose and were filed before NECC's petition in bankruptcy are subject to the automatic stay provisions of 11 U.S.C. § 362(a) (1).

147. NECC has ceased operations.

148. NECC is unable to pay its debts as they fall due.

149. NECC is unable to pay its debts in the ordinary course of its business.

150. NECC's liabilities exceed its assets.

151. NECC is insolvent.

152. On July 24, 2013, the United States Bankruptcy Court for the District of Massachusetts in In re: New England Compounding Pharmacy, Inc., No. 12-19882-HJB, ordered that with respect to certain claims, including those asserted here, NECC is presently insolvent and has been insolvent at all times since the petition date.

153. The Tennessee Defendants as set forth herein in paragraphs 16-32, at all times material hereto, combined with one another in concert as a joint venture to own, operate, manage, control and maintain Defendant Saint Thomas Neurosurgical. For the purposes of this Complaint, Saint Thomas Neurosurgical is also referred to and considered a Tennessee Defendant.

154. Saint Thomas Neurosurgical procured the MPA injected into Ms. Peay from NECC.

155. NECC's product was defective and unreasonably dangerous when it left NECC's control because it was contaminated with lethal pathogens, and it was in substantially the same condition at the time that Saint Thomas Neurosurgical injected it into Ms. Peay on September 7, 2012.

156. Saint Thomas Neurosurgical charged Ms. Peay for the epidural steroid injection it administered to her.

157. Saint Thomas Neurosurgical acted as a seller or distributor of MPA compounded by NECC when it sold and administered epidural steroid injections to patients, including Ms. Peay.

158. Saint Thomas Neurosurgical was engaged in the business of selling MPA compounded by NECC.

159. Accordingly, Saint Thomas Neurosurgical is a "seller" as defined by Tenn. Code Ann. § 29-28-102(7).

160. Tenn. Code Ann. § 29-28-106(4) and/or (5) authorizes Ms. Peay to prosecute product liability claims against the Tennessee Defendants, operating Saint Thomas Neurosurgical, as the seller of the MPA injected into Ms. Peay because the compounder of the product, NECC, cannot be served with process in this state and/or has been or will be judicially declared insolvent.

161. The MPA that Saint Thomas Neurosurgical injected into Ms. Peay was unreasonably dangerous and defective at the time it left its control because it was contaminated with lethal pathogens.

162. Specifically, the MPA was in a defective condition and unreasonably dangerous at all relevant times because it was unsafe for normal or anticipated handling as defined by Tenn. Code Ann. § 29-28-102(2).

163. The MPA sold and distributed by Saint Thomas Neurosurgical was neither merchantable nor fit for the purpose for which it was produced and sold. Accordingly, Saint Thomas Neurosurgical breached its warranties, both express and implied, as stated in Tenn. Code Ann. §§ 47-2-313, 47-2-314 and 47-2-315, including its warranty of fitness for a particular purpose.

164. The Tennessee Defendants are strictly liable for the injuries and losses caused by the unreasonably dangerous and defective steroids injected into Ms. Peay.

DAMAGES

165. As a direct and proximate result of the Defendants' wrongful conduct as described above, Ms. Peay has suffered physical injuries, physical and mental pain and suffering, mental anguish, and loss of enjoyment of life.

166. The long term effects of Ms. Peay's condition are unknown.

167. Ms. Peay remains under the care of physicians and has incurred and will continue to incur medical and other expenses.

PUNITIVE DAMAGES

168. The above described acts and omissions on the part of the Defendants were reckless and intentional. Defendants were aware of, but consciously disregarded, a substantial and unjustifiable risk of such a nature that their disregard constitutes a gross deviation from the standard of care that an ordinary person would exercise under all the circumstances. Ms. Peay is therefore entitled to an award of punitive damages against the Defendants.

**CAPS FOUND IN TENN. CODE ANN. § 29-39-102 AND § 29-39-104
ARE UNCONSTITUTIONAL AND VOID *AB INITIO***

169. On October 1, 2011, the Tennessee Civil Justice Act went into effect, enacting “caps” in all Tennessee personal injury cases for non-economic damages and punitive damages. Tenn. Code Ann. § 29-39-102; and Tenn. Code Ann. § 29-39-104. Under that Act, Ms. Peay’s non-economic damages are purportedly capped at \$750,000, and her ability to recover punitive damages is capped at twice the compensatory damages up to a maximum of \$500,000.

170. Tenn. Code Ann. § 29-39-102 and Tenn. Code Ann. § 29-39-104 are unconstitutional deprivations of Ms. Peay’s constitutionally protected right to trial by jury. Those provisions violate Article I, Section 6 of the Constitution of the State of Tennessee, which provides that the right of trial by jury shall remain inviolate. In addition, the subject statutory caps violate Article I, Section 17 of the Tennessee Constitution which states that all courts shall be open, and every man shall have a remedy for injury done by due course of law and without denial or delay. The subject statutory caps usurp the powers of the Judicial Branch in violation of Article II, Sections 1 & 2 of the Tennessee Constitution. In addition, the subject statutory caps violate Article XI, Section 16 of the Tennessee Constitution which indicates that the rights of citizens articulated in Tennessee’s Bill of Rights “shall never be violated on any pretense whatever . . . and shall forever remain inviolate.” Therefore, Ms. Peay requests a declaration, pursuant to Tenn. Code Ann. § 29-14-103, that the statutory caps are void *ab initio* and of no force and effect.

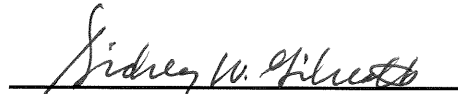
171. Pursuant to Tenn. Code Ann. § 29-14-107, a copy of this Complaint is being served on the Attorney General of the State of Tennessee, notifying the State of Tennessee Attorney General that Ms. Peay is challenging the constitutionality of Tenn. Code Ann. § 29-39-102 and Tenn. Code Ann. § 29-39-104.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, Joan Peay, requests the following relief:

- A. A judgment for compensatory damages in an amount to be determined by the trier of fact;
- B. A judgment for punitive damages in an amount to be determined by the trier of fact;
- C. A jury to determine all disputed factual issues;
- D. For costs of this cause; and
- E. For such further relief as the Court may deem just and proper.

Respectfully submitted,



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